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VIA E-MAIL

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Re: Response to Bayer's "Request for Clarification" of EPA's February 15, 2022 Decision Concerning Bayer's Petition to Deny Sharda's Technical Prothioconazole Registration

Dear Ms. Stoner:

This letter constitutes the Response of Sharda Cropchem Ltd. ("Sharda") to the "request for clarification" submitted by Bayer CropScience LP's ("Bayer") regarding the U.S. Environmental Protection Agency's ("EPA") Decision dated February 15, 2022 concerning Bayer's Petition to Deny Sharda's Application to Registration Prothioconazole Technical ("Bayer's Request"). Bayer's Request is unwarranted and without merit, and should not delay the Agency in granting Sharda's technical prothioconazole registration. To the extent EPA elects to entertain Bayer's Request, Sharda provides this Response.

A. Background

In May 2021, Bayer submitted a Petition to Deny Sharda's application to register a technical prothioconazole product and any applications to register end-use products containing that Sharda's prothioconazole technical. In its Decision dated February 15, 2022 (the "Decision"), EPA found that Sharda needed to cite some, but not all, of the studies in the Petition. EPA's Decision further provided that if Sharda added the studies required to its data matrix, made an offer to pay for them and submitted documentation to EPA, "the Agency will consider this petition resolved." Decision at 1. Sharda did so within the 15 days in accordance with 40 C.F.R. § 152.99(c)(2), and as provided in the Decision. As such, Bayer's Petition is resolved and the Agency's Decision is final.

There is no basis or need for EPA to "clarify" its Decision. In some cases, Bayer's complaints relate to studies for which it concedes it received an offer to pay from Sharda so there is nothing further for the Agency to resolve or "clarify"; in others, Bayer complains about studies

that were beyond FIFRA's 15-year compensation period even if measured from the "look-back" date Bayer advocates, and that therefore were never a part of its Petition.

The balance of Bayer's disagreements with EPA's Decision concerning the data Sharda must cite in the data matrix supporting its application for a technical prothioconazole registration are premised on its effort to conflate (end use) pesticide labels with data, or ignore the clear distinction that EPA has recognized repeatedly between data that are required to satisfy data requirements – for which citation is required – and data that EPA may review for various scientific regulatory purposes – for which citation is not. As explained when it promulgated regulations under FIFRA data citation and compensation scheme:

[T]here is an *important distinction* in the statute between (1) EPA review under FIFRA § 3(c)(1)(F) to determine whether the applicant has satisfied the requirements that specify how an application must be supported by submission or citation for data, and (2) EPA review of data to determine whether to approve a properly supported application on risk/benefit grounds."

49 Fed. Reg. 30884, 30887 (Aug. 1, 1984) (emphasis added); *see generally* Sharda Response to Bayer's Petition to Cancel (Sept. 14, 2021) (Exhibit 1). Thus, the Agency must engage in "two separate data review functions" in determining whether a proposed pesticide meets the registration standards in FIFRA § 3(c)(5). *Id.* at 30887-88. The first data review requires the Agency to determine whether the applicant has cited or submitted sufficient data to satisfy applicable data requirements to meet the standard in § 3(c)(5)(B). *Id.* at 30887. The second data review function requires EPA to consider any and all available data to determine whether the pesticide meets the risk/benefit criteria set forth in § 3(c)(5)(C) and (D). *Id.* at 30887-88, 30902. Critically, whereas EPA's consideration of data in the first review is governed by FIFRA's data compensation provisions, its consideration of the broader universe of data to make the risk/benefit determinations required by subparagraphs (C) and (D) is not. *Id.*

Sharda's application to register a technical prothioconazole product is not the first time Bayer has tried – and failed – to expand the data that must be cited beyond that necessary to satisfy the applicable data requirements. By way of example, over a decade ago, the Agency rejected such an attempt by Bayer:

Bayer also asserts that because [the follow-on's] application does not cite to or contain all the data necessary for registration, EPA does not have available to it data necessary to make the required [no unreasonable risk] finding[s] under FIFRA. Not so. It is well established that for purposes of making its risk/benefit determination, EPA is not limited to data cited or provided by the applicant.

Letter Decision (Imidacloprid) at 9 n.5 (Exhibit 2). As noted, EPA has repeatedly affirmed that follow-on applicants need only cite data necessary to satisfy applicable data requirements, and that compensation is not required for data that may be considered by the Agency for other purposes. *See, e.g.,* Letter Decision (Permethrin) at 3-4 ("Although EPA necessarily takes into account all relevant information available to the Agency when evaluating an application for a particular use of a pesticide, it does not follow that an applicant must offer to pay compensation

for all such data. There is an important distinction between EPA review of data that an applicant must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(F), and EPA review of data for other scientific purposes”) (Exhibit 3); Letter Decision (Spray Drift Task Force) at 1-2 (“[A]n applicant is obligated to submit or cite all data necessary to satisfy EPA data requirements; applicants are not required to submit or cite all data that EPA may evaluate for the purpose of determining whether the pesticide satisfies the FIFRA unreasonable adverse effects standard or the FFDCA section 408 safety standard”) (Exhibit 4); *see also* Letter Decision (GRETf) at 1 (“You are correct that EPA’s consideration of data in making a registration review or registration determination does not by itself compel submission or citation of data. EPA must first require those data.”) (Exhibit 5).

Bayer’s complaints also relate to data submitted during Registration Review absent a requirement to do so in a data call-in (“DCI”). Here too, Bayer’s criticisms echo questions and comments raised by data owners more than a decade ago that were addressed by EPA at that time. *See* 71 Fed. Reg. 45720, 45723 (Aug. 9, 2006). In the Preamble to the Final Rule promulgating regulations implementing the Registration Review process in FIFRA § 3(g), EPA notes that data owners that raised the same concern Bayer now raises, concerning the compensation status of data characterized by EPA as provided to EPA during the Registration Review process outside the requirements of a DCI and, thus, in EPA’s words, “‘voluntarily’ submitted.” *See id.* (“Industry comments asked that the proposed rule clarify the data compensation status of information voluntarily submitted in response to registration review”). EPA explained that:

If a company submits data or information to the docket voluntarily (as opposed to providing these data or information in response to a DCI), such data are not “required” data eligible for protection under the statute.

Id. at 45723. EPA added that if the Agency determines during the course of Registration Review that it “must rely” on an item of “voluntarily submitted” data to support the continued registration of the pesticide – which EPA called a “compensable event” – the Agency will notify all registrants, either in a DCI or in a registration review decision document, that the data are now required and that other registrants then will have the opportunity to cite and offer to pay for the data, or to submit data to satisfy the new data requirement. *Id.*

The authorities reviewed above make clear that Bayer’s reading of the scope of EPA “data requirements” continues to be overbroad. Even if there were some basis for EPA to “clarify” its Decision, Bayer’s arguments provide no basis for it to do so. Instead, Bayer’s “Request for Clarification” appears to be nothing more than an effort to delay EPA in granting Sharda’s follow-on prothioconazole technical registration. EPA should not allow the process by which it decides a petition to deny to be corrupted in this manner, particularly when EPA has addressed and fully resolved Bayer’s Petition.

B. The Data and other Items at Issue in Bayer's "Request for Clarification"

1. Environmental Fate Studies

MRIDs 50917601 and 50917602

Sharda agreed to cite these two studies and provided Bayer with an offer to pay for them on February 15, 2022. Bayer Request, Exhibit E. As Bayer does not dispute that it has received an offer to pay for MRIDs 50917601 and 50917602, there is nothing further for EPA to clarify or require with regard to these studies.

MRIDs 46246507, 46246511, 46246512, 46246515 and 46246516

Bayer appears confused with regard to these studies. Although cited in Sharda's original application, no offer to pay was required for them because Bayer submitted them to EPA in April 2004. As explained below, there is a dispute between data owners and follow-on applicants as to whether FIFRA's 15-year compensability period is measured back from the date of application or date of registration, and FIFRA arbitrators sometimes are required to address this issue. However, when Sharda submitted its prothioconazole technical registration application in September 2020, MRIDs 46246507, 46246511, 46246512, 46246515 and 46246516 were more than 15 years old regardless of how the 15-year period is measured. As such, they were not included in Sharda's September 2020 offer to pay, nor were they included in Bayer's Petition or its October 2021 submission in further support of its Petition, notwithstanding that Bayer never received an offer to pay for them (because it is not entitled to receive one). As these studies were not a subject of Bayer Petition, and Bayer has no legal right to an offer to pay for them, so there is nothing for the Agency to "clarify."

2. Subpart O Residue Studies

48024903

Bayer notes that EPA required Sharda to cite 48024904, which is a residue study concerning a mixture on potatoes. It then complains that EPA did not require Sharda to cite MRID 48024903, which is another study addressing the same subject. Bayer does not explain why Sharda should be required to cite two seemingly duplicative studies concerning mixture data on potatoes. As Sharda used the selective method and cannot be required to cite duplicative data, there is nothing for EPA to "clarify."

MRIDs 46841001 and 46841002

Bayer's Request with respect to MRIDs 46841001 and 46841002 is much ado about nothing. More troubling, however, is that it reflects an attempt by Bayer to involve the Agency in a decision that is not Agency's to make and that may be before arbitrators in a *currently-pending arbitration* that Bayer initiated against Sharda under its September 2020 offer to pay concerning prothioconazole.

As Bayer admits and as reflected in Exhibit B to Bayer's Request, Sharda's letter to Bayer dated September 30, 2020 includes an offer to pay for both MRIDs 46841001 and 46841002. Bayer Request at 4 and Exhibit B. Receipt of an offer to pay for a study meets the prerequisite for Bayer to assert a claim compensation for that study in an arbitration initiated under FIFRA. FIFRA §3(c)(1)(F)(iii). Bayer fails to disclose to the Agency that, on August 3, 2021, it initiated arbitration against Sharda for compensation under the September 2020 offer to pay that includes MRIDs 46841001 and 46841002. Bayer Demand for Arbitration (Aug. 3, 2021) (Exhibit 6).

Notwithstanding that Bayer has received an offer to pay for MRIDs 46841001 and 46841002 and has initiated arbitration against Sharda under that offer, Bayer complains that Sharda's subsequent offers to pay for prothioconazole data provided to Bayer in September 2021 and February 2022 omit MRIDs 46841001 and 46841002. This is because these studies were submitted to EPA in May 2006, and it is Sharda's position that they need not be included in an offer to pay after May 2021. As EPA has recognized, data can "age out" of compensability between the date an application was submitted and the date EPA grants the registration. When promulgating regulations under FIFRA in 1979, EPA explained that "an applicant may have no duty to actually *pay* [emphasis in original] compensation for much of the data upon which an application is based. The statute places in the non-compensable category ... all data submitted more than 15 years before the *approval* of the application in question" 44 Fed. Reg. 27945, 27949 (May 11, 1979) (emphasis added). Although the 1979 regulations were struck down for unrelated reasons, EPA reiterated that "data submitted more than 15 years before the approval of the [follow-on's] application" are not compensable when it re-proposed the data reliance regulations in 1982. 47 Fed. Reg. 57635, 57643 (Dec. 27, 1982). Other authorities also support the conclusion that compensability – "the duty to actually *pay* compensation" in EPA's words – is properly measured from the registration date.

Sharda understands that it is Bayer's position that compensability is measured from the date of Sharda's original application or offer to pay, and that MRIDs 46841001 and 46841002 were still within the 15-year compensability period under that view. Whether FIFRA's 15-year compensability period is measured from the date of a follow-on application is submitted to EPA or the date that follow-on application is granted is a matter of dispute between data owners and follow-on registrants. Absent an agreement, it is an issue to be decided by arbitrators in the arbitration process. FIFRA arbitrators decision on this issue have gone both ways, but the bulk of the authority finds that compensability is measured from the date of registration, not application as Bayer submits. In fact, the most comprehensive analysis of this issue by FIFRA arbitrators occurred in an arbitration brought by Bayer. *See Bayer v. Albaugh*, Order on Motion to Dismiss (Exhibit 7). There, in a decision granting the follow-on registrant's motion to dismiss data more than 15-years "old" from the date of its registration (and in a subsequent decision denying Bayer's Motion for Reconsideration), the arbitrators went through a detailed analysis that included the statute, regulations and legislative history to find that FIFRA's 15-year compensability period is measured from registration, not application. *Id.*; *see also Bayer v. Albaugh*, Decision on Motion for Reconsideration (Exhibit 8).

In any event, if Bayer wishes to assert a claim for compensation for MRIDs 46841001 and 46841002, the statutory prerequisite for it to do so is met by Sharda's September 2020 offer

to pay under which Bayer already has initiated arbitration. There is nothing further for EPA to do or “clarify.” EPA’s role under the regulations concerning data submitters’ rights and the petition procedure is to ensure that an offer to pay is provided to the extent it determines one is required. As Bayer concedes, Sharda provided an offer to pay for MRIDs 46841001 and 46841002 in September 2020. If Bayer claims compensation for MRIDs 46841001 and 46841002 in the arbitration it has initiated, the arbitrators will decide if Sharda must pay compensation for studies included in Sharda’s original offer that were submitted to EPA more than 15 years before the date Sharda receives its registration.

3. Pollinator Studies

50489204, 50489205 and 50521803

In finding that Sharda is not required to cite these studies, EPA noted that the data were not reviewed by EFED and therefore not required. Bayer’s argument appears premised on an effort to ignore that EPA has a detailed reviewed process by which it evaluates the validity and significance of submitted data. It remains the case that the data are characterized by EPA as “under review” in its Draft Risk Assessment; EPA has not completed that review and determined them to be “acceptable” or even “supplemental.” *See* Bayer Exh. F at 34, 131.

More significantly, EPA also has not determined the studies are *required* to address a data requirement, either in the 2017 DCI or through other procedures mandated by FIFRA. *See* 71 Fed. Reg. at 45723 (data submitted to EPA outside a DCI requirement “are not ‘required’ data eligible for protection”; if EPA later makes a determination that it “must rely” on them, it “will notify all registrants, either in a DCI or in a registration review decision document, that the data are now required and that other registrants then will have the opportunity to cite and offer to pay for the data, or to submit data”). In that regard, Bayer acknowledges that the studies “relate” to SS-1342 in the 2017 DCI. Bayer Request at 5. SS-1342, however, is a guideline that EPA *reserved* rather than required in the 2017 DCI. Specifically, with respect to SS-1342 and other Tier 2 pollinator data, the DCI provides that “[t]he need for a semi-field test for pollinators ... will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.” Prothioconazole Generic Data Call-In (Exhibit 9). Bayer continues to ignore that the 2017 DCI provides that EPA will determine the need for Tier 2 pollinator studies at a later date, and EPA subsequently concluded that Tier 2 studies are *not* required. Prothioconazole Interim Registration Review Decision at 23 (Exhibit 10). Accordingly, Bayer’s concession that MRIDs 50489204 and 50489205 relate to SS-1342 – a data requirement EPA has not imposed on applicants/registrants – demonstrates that Sharda is not required to cite the studies.

In short, the 2017 DCI does not require Sharda to submit or cite Tier 2 pollinator studies, and EPA has not determined that these Tier 2 studies submitted outside a DCI requirement are now required. Further, even assuming EPA had required Tier 2 pollinator data, EPA has not determined the studies acceptable to address that requirement. As such, there is nothing for EPA to clarify with respect to these studies.

50521801 and 50521802

EPA properly found that these studies are supplemental, and also that they were conducted on bumblebees rather than honeybees. Because honeybee is the test species required for the pollinator studies, they do not satisfy any pollinator data requirements and cannot be required.

Rather than dispute these determinations, Bayer instead asks that EPA “clarify” its position with respect to data or studies that may be requested from a registrant through means other than a DCI or imposition of a data requirement. There is no need for EPA to do so, as the process by which EPA may require other registrants to cite data that EPA previously requested from a registrant and/or that that registrant voluntarily submitted is well established and clear, and Bayer long has been on notice of this process.

As noted, the Agency comprehensively addressed this subject in the Preamble to the Final Rule promulgating regulations implementing the Registration Review process in FIFRA § 3(g). *See* 71 Fed. Reg. 45720, 45723 (Aug. 9, 2006). There, EPA distinguished between data submitted in response to a DCI requirement, and data submitted during Registration Review outside the requirements of a DCI and provided data submitters with notice as to how such data may be treated for compensation purposes. *See id.* (“If a company submits data or information to the docket voluntarily (as opposed to providing these data or information in response to a DCI), such data are not “required” data eligible for protection under the statute”). EPA characterized the latter as “voluntarily submitted” and explained that they are not ““required” data eligible for protection under the statute.” *Id.* However, if the Agency determines during the course of Registration Review that it “must rely” on an item of “voluntarily submitted” data to support the continued registration of the pesticide – which EPA called a “compensable event” – the Agency will notify all registrants, either in a DCI or in a registration review decision document, that the data are now required and that other registrants then will have the opportunity to cite and offer to pay for the data, or to submit data to satisfy the new data requirement. *Id.* The Agency has made no such determination that these studies are required in its Prothiconazole Interim Registration Review decision, nor has it issued a DCI requiring them.

4. “Directions for Use” Items

Bayer requests that EPA “reconsider” (rather than “clarify”) its Decision regarding to Bayer’s so-called “Directions for Use” (“DFU”) items. Bayer Request at 9. There is no legal basis for such a request, much less the relief Bayer seeks.

Bayer points out, as it did in its Petition that the Agency already addressed, that DFU are a requirement under the residue chemistry guidelines and OPPTS 860.1200. This requirement, however, is addressed by submission of a *label*, not submission of *data*. OPPTS 860.1200(c)(1) (“The directions for use are ordinarily contained in specimen labeling submitted concurrently for registration under FIFRA”); *cf.* Bayer Petition at 15 (conceding that Directions for Use are “submitted to EPA by Bayer in the form of specimen end-use labels that detail the required directions for use for each crop use”). Attempting to address this fatal flaw in its argument, Bayer then makes the conclusory assertion that DFU data [sic] are “data submissions.” Bayer

Request at 7. FIFRA, however, makes a clear distinction between data and labels containing the directions for use of a product. FIFRA § 3(c)(1)(F), for example, requires the submission of/citation to data and contains a compensation provision (FIFRA § 3(c)(1)(F)(iii)). In contrast, the provision of FIFRA requiring submission of a label – FIFRA § 3(c)(1)(C) – has no compensation provision. To accept Bayer’s argument that data and labels are one in the same would require ignoring the structure and content of FIFRA. It also would dramatically expand FIFRA’s data citation and compensation scheme beyond that enacted by Congress, by adding a right to compensation for *labels* that Congress did not see fit to include when it provided compensation for *data*.

Bayer disputes the conclusion in EPA’s Decision that the data matrix submitted in connection with Sharda’s technical prothioconazole application is not required to cite the “DFU items.” However, Bayer does not – and cannot – dispute the substance of the Agency’s Decision that “Directions for Use studies are not studies EPA would expect to be cited on any data matrix” (Decision at 4-6). In fact, data matrices *submitted by Bayer* to support its own technical prothioconazole registration do not identify 860.1200 or Directions for Use as a data requirement, nor do they cite any of the tolerance petitions Bayer now claims must be cited to support a prothioconazole registration. *See, e.g.,* Bayer Technical Prothioconazole Data Matrices (Exhibits 11-14). Because FIFRA does not preclude a registrant from citing data that EPA does not actually require to support a registration, a registrant’s *inclusion* of a data requirement or data item on its data matrix does not establish that EPA required it. However, a registrant’s *exclusion* of a data requirement or data item from its data matrix shows that that registrant does not contend that it is required. *See* 40 C.F.R. § 152.90(a)-(b) (requiring applicant to identify on its data matrix all applicable requirements and cite data to satisfy each). More significantly, since EPA is legally obligated to determine the data requirements applicable to a registration application and confirm that they are met prior to approval, its approval – particularly repeated approval – of a registration based on data matrices do not include DFU items (or tolerance petitions) also reflects EPA’s determination that they are *not* required.

Further, EPA’s determination that “Directions for Use studies are not studies EPA would expect to be cited on any data matrix” (Decision at 4-6) also is supported by the requirement that FIFRA requires that Sharda submit its *own* labels. *See* FIFRA § 3(c)(1)(C) (“Each applicant for registration shall file a statement which includes ... a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use). Even putting aside the lack of citation and compensation provisions applicable to labels in FIFRA, the statute does not authorize EPA to rely on *Bayer’s label* in order to satisfy the requirement of the residue chemistry guidelines and OPPTS 860.1200 that *Sharda* submit a label.

Bayer also attempts to avoid the distinctions in FIFRA between data and labels by conflating directions for use contained on end use labels with tolerance petitions. The content of the tolerance petitions on which it relies, however, are the directions for use of an end use product reflected on its label. *See, e.g.,* Bayer Request at 7-8 (“Section B of the tolerance petitions indicate the amount, frequency, and timing of the application of the pesticide chemical, i.e., the directions for use, dosage rates, number of applications, restrictions, pre-harvest intervals, and times of application proposed for inclusion on the label of the product”). Similarly, the review referenced in Bayer’s Request and attached as Exhibit I concerns review of

a label in connection with separately submitted residue data. *See* Bayer Request, Exhibit I at 1, 4 (“Use directions for the label ... are from a draft label.... The proposed label is adequate to allow evaluation of the residue data submitted in support of this petition.”).”

Bayer’s misguided claim that EPA reviews DFU data suffers from the same flaw. The subject matter of PR Notice 96-4 to which Bayer refers is “*Label Statements Involving Product Efficacy and Potential for Harm to Property*.” PRN 96-4 (emphasis added). *see also id.* (“This notice explains EPA procedures in approving pesticide labels that include claims relating to the efficacy of agricultural pesticides...”). Again, Bayer conflates labels and with data, but as this PRN demonstrates, they are separate and distinct. *See, e.g., id.* (waiving the requirement for submission of *data* supporting efficacy claims in connection with *labels* submitted to EPA for approval).

This reveals another reason why there is no basis for EPA to reconsider its finding and recognition that “DFU studies” are not required to be cited on data matrices. EPA has expressly waived the requirement that applicants submit or cite data related to directions for use for most pesticides including prothioconazole. Trials from which directions for the uses, application, rates, timing and the like may be derived concern “product performance.” As EPA explains:

The term “product performance” refers to all aspects of a product’s effectiveness and usefulness. Any evaluation of product performance is conducted in light of expressed and implied labeling claims or recommendations concerning pests, sites, methods of application, application equipment, dosage rates, timing and number of applications, use situations, nature and level of pest control, duration of pest control, compatibility with other chemicals, benefits and/or adverse effects of product use, compatibility of common practices associated with the sites, active ingredient status of chemicals in the formulation, and equipment.

OPPTS 810.1000, EPA Product Performance Test Guidelines at 1, *available at* [[HYPERLINK "https://downloads.regulations.gov/EPA-HQ-OPPT-2009-0150-0002/content.pdf"](https://downloads.regulations.gov/EPA-HQ-OPPT-2009-0150-0002/content.pdf)]. The Test Guidelines define “effectiveness” as follows:

Effectiveness refers to a product’s ability to control the specific target pest or produce the specified plant or animal response when the product is applied in accordance with the label directions, precautions, and limitations of use. The term effectiveness, as used in this guideline, is synonymous with the term efficacy.

Id. at 4. EPA’s Guidelines go on to “provide guidance concerning the methodology of efficacy testing and the content of test reports,” while cautioning that “they *do not* independently establish any *data submittal requirements*.” *Id.* at 5 (emphasis added). Once again, this reflect the distinction between directions for use expressed on a label (or reflected in a tolerance petition) and the submission of data.

Just as EPA’s Product Performance Test Guidelines establish that trials from which directions for use may be derived constitute product performance/efficacy tests, they also confirm that these tests are not required to be submitted to EPA in support of registration for

agricultural herbicides. This is because “[t]he Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pests that may pose a threat to human health.” EPA Product Performance Test Guidelines at 2. In fact, EPA waived the requirement to submit or cite product performance/efficacy data for pesticides such as prothioconazole more than 40 years ago, in 1979, in response to the 1978 FIFRA amendments. See 44 Fed. Reg. 27932, 27938-40 (May 11, 1979). EPA explained that the waiver would “reduce the amount of [Agency] resources devoted to reviewing product performance” data, noting that “the efficacy of agricultural pesticides can be effectively regulated by the marketplace.” *Id.* at 27938. For those cases where marketplace regulation proved to be inadequate, EPA “reserve[d] the right to request submission of efficacy data” through data call-ins issued under FIFRA § 3(c)(2)(B). *Id.* at 27939.

EPA’s waiver of the requirement for registrants to submit or cite efficacy/performance data currently appears in FIFRA’s regulations at 40 C.F.R. pt. 158, Subpart E—Product Performance (CA54). In particular, § 158.400(e) n.1 states in pertinent part: “The Agency has waived all requirements to submit efficacy data unless the pesticide product bear a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user ... or vertebrates ... that may directly or indirectly transmit diseases to humans.” Prothioconazole is an agricultural pesticide and is not used to control human health pests (such as rodents, ticks, and pathogenic bacteria and viruses). As such, like most other pesticides, prothioconazole is subject to EPA’s efficacy data waiver. 40 C.F.R. § 158.400(e) n.1. EPA has stated repeatedly that the efficacy of agricultural pesticides such as prothioconazole is “effectively regulated by the marketplace” and that, accordingly, it does not evaluate performance data for such products. *See, e.g.* PRN 96-4 (EPA waiver for product performance data based on, *inter alia*, “the high level of knowledge concerning pesticidal efficacy that prevails in the agricultural community, the existence of means for communicating efficacy information to users, the organizational expertise of the Department of Agriculture, the extension services, and the universities, and the stake the industry has in marketing products that are efficacious”) (citing S. Rep. 95-334, 95th Cong., 1st Sess. 20 (July 6, 1977)).

As EPA itself has recognized, the Agency’s waiver of the requirement to submit product performance data relieves follow-on registrants from the requirement to compensate original registrants for those data, whether or not the data were ever submitted to the Agency. *See, e.g.*, 47 Fed. Reg. 57624, 57646 (Dec. 27, 1982) (“Much of the existing data are not compensable, because ... efficacy data are no longer reviewed by the Agency”).

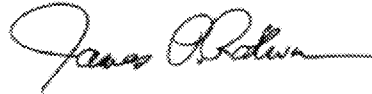
Finally, EPA’s Decision that DFU items are not required to be cited on the data matrix submitted with Sharda’s technical prothioconazole registration application also is consistent with the fact that the directions for use to which Bayer refers – “the recommended amount, frequency, method, and time of application of the pesticide chemical” (Bayer Request at 7) – concern the instructions for use of an *end use* pesticide product. *See, e.g.*, Bayer Pet. at 15 (asserting “DFU data” “were submitted to EPA by Bayer in the form of specimen *end use* labels that detail the required directions for use for each crop”) (emphasis added); Bayer Pet., Exhibits J-R (petitions submitted to establish tolerance for Bayer’s end use prothioconazole products). Sharda’s proposed label for technical prothioconazole does not contain instructions for the “amount, frequency, method, and time of application” on the product because it is not used or applied as

an end use product. Accordingly, even if the DFU guideline required the submission/citation of data rather than submission of a label, Bayer's "specimen end use labels that detail the required directions for use for each crop" and/or tolerance petitions, are not relevant to the data matrix submitted to support Sharda's application for a technical prothioconazole registration.

C. Bayer's Request for "Clarification" Concerning EPA's 75-day Deficiency Policy

Bayer also requests that EPA clarify its policy with regard to 75-day deficiency letters. Sharda's pending application to register technical prothioconazole is not the appropriate context for EPA to do so. The requirement for Sharda to cite the additional studies identified in EPA's Decision is a result of the Agency's Decision on Bayer's Petition to Deny, not a 75-day deficiency letter. Moreover, Bayer's complaint that EPA's Decision provides Sharda with an opportunity to cite the additional studies determined to be required as a result of Bayer's Petition to Deny is not well founded. By regulation, EPA is required to provide Sharda with 15 days to cite any studies determined to be required as a result of a Petition to Deny. 40 C.F.R. §152.99(c)(2). EPA would be in violation of its own regulations if it declined to allow Sharda to do so. Sharda cited the additional studies required in the Decision within the period permitted by the Decision and 40 C.F.R. § 152.99(c)(2). Accordingly, Bayer's "Request for Clarification" should not delay EPA decision on Sharda's technical prothioconazole registration.

Respectfully submitted,



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